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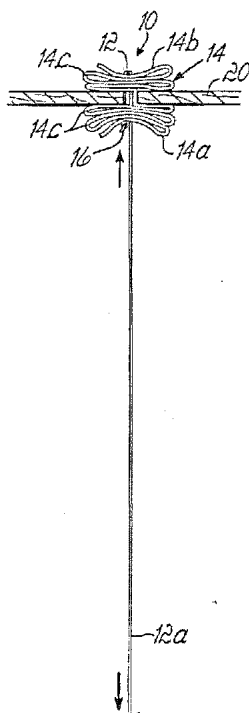
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- (71) Applicant (for all designated States except US): MITRALIGN, INC. [US/US]; 3 Highwood Drive, 2nd Floor, Tewksbury, MA 01876 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): SUGIMOTO, Hiroatsu [JP/US]; 1560 Cambridge Street, Apt. 2, Cambridge, MA 02139 (US). CALL, Aaron, M. [US/US]; 305 Dutton Street, #414, Lowell, MA 01854 (US). LEISING, Karl, R. [US/US]; 3 Playhouse Circle, Hampton, NH 03842 (US).
- (74) Agents: ROONEY, Kevin, G. et al.; Wood, Herron & Evans, L.L.P., 2700 Carew Tower, Cincinnati, OH 45202 (US).
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[Continued on next page]

(54) Title: TISSUE ANCHOR AND METHODS OF USING THE SAME



(57) Abstract: A tissue anchor (10) includes an anchor member (14) formed from a generally flexible material. An activation member, which may be a tensioning member (12), causes proximal and distal end portions (14a, 14b) of the anchor member (14) to move toward each other into a shortened configuration suitable for anchoring against the tissue (20). The tissue anchor (10) can optionally be deployed and activated using a catheter device (50).

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TISSUE ANCHOR AND METHODS OF USING THE SAME

Technical Field

[0001] The present invention generally relates to tissue anchors and, more particularly, anchors and methods of using such anchors to secure an element or otherwise provide an anchor point to biological tissue and/or to secure at least two tissue portions together.

Background

[0002] Many different surgical procedures require that an anchor be used to either establish a strong point of connection for other securing elements or devices relative to a tissue location in a patient, and/or to secure two or more tissue layers (i.e., portions together. In this regard, the term "anchor", as used herein, is not to be limited to any particular type of tissue fastening or securement application but, rather, encompasses any hard and/or soft tissue-to-tissue securement, tissue-to-device securement, or any other tissue securement application.

[0003] One particular area that has received attention in recent years is that of catheter-based surgical procedures. Various tissue anchors have been developed for purposes of deployment and securement with catheter-based technology. However, there are still limitations in current technology. For example, insertion size versus deployment size must be strictly controlled due to the need for catheter diameters to be maintained relatively small. Many catheter-based tissue anchor systems have very specialized uses and are not versatile for use in many different tissue fastening or securement operations.

[0004] There is generally a need for a simpler, more versatile tissue anchor which may be deployed and securely fastened to tissue in a catheter-based operation or a non-catheter-based operation.

Summary

[0005] In one aspect, the invention provides a tissue anchor comprising a generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue. The anchor member includes a proximal end portion, a distal end portion, and a compressible intermediate portion between the proximal end portion and the distal end portion. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member may be pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration. In the shortened configuration, the compressible intermediate portion of the anchor member can compress or shorten and thereby adjust to the thickness of the tissue between the proximal and distal end portions.

[0006] In another aspect of the invention, a tissue anchor is provided comprising a flat, generally flexible anchor member capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member is capable of

~~being pulled to cause the~~ anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration.

[0007] In a further aspect of the invention, a tissue anchor is provided comprising a flat anchor member formed from a strip of fabric material and capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue. A tensioning member is operatively connected to the anchor member such that the anchor member can slide relative to the tensioning member. The tensioning member is capable of being pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration. A lock member is provided for securing the anchor member in the shortened configuration.

[0008] In a further aspect of the invention, a tissue anchor is provided comprising a flat, generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration suitable for deployment through a catheter and a shortened configuration suitable for anchoring against the tissue. A tensioning member is operatively connected to the anchor member such that the anchor member may slide relative to the tensioning member. The tensioning member is capable of being pulled to cause the anchor member to move relative to the tensioning member from the elongate configuration to the shortened configuration against the tissue.

[0009] In another aspect of the invention, a tissue anchor is provided comprising a flat elongate strip formed from a generally flexible material and having proximal and distal end portions. A tensioning member having first and second ends is operatively connected to the elongate strip such that pulling on the first end of the tensioning member causes the proximal and distal end

portions of the elongate strip to move toward each other to a shortened configuration suitable for anchoring against the tissue.

[0010] In certain aspects, the anchor member is advantageously formed as a flat, generally flexible strip of material, while in other aspects it need not be a flat strip but may have other shapes, such as tubular, that may or may not be capable of assuming a flat shape. Various optional features may be incorporated into any or all of the various embodiments of the tissue anchor. For example, the tissue anchor may be formed from a material selected from at least one of: natural fibers, synthetic fibers, polymers, and metals. Such materials may be absorbable or nonabsorbable, and may be radiopaque or at least partially radiopaque. The tensioning member may further comprise a suture, or any other suitable flexible, semi-rigid or rigid tensioning member. The tensioning member may include a stop member engaged with the anchor member, such as a knot in the tensioning member, or a separate stop member (e.g., a crimp) engageable with the anchor member. The tensioning member may, for example, extend through the anchor member at multiple locations between the proximal end portion and the distal end portion. Such coupling of the tensioning member and the anchor member may be configured in many different manners depending, for example, on the desired configuration of the anchor member upon pulling the tensioning member and moving the anchor member into the shortened configuration. In one embodiment, at least one fold is formed upon pulling the tensioning member. Multiple folds may be formed in a generally zig-zag or accordion fashion. A lock member may be provided and engageable with the tensioning member to retain the anchor member in the shortened configuration. The tissue anchor may include at least one radiopaque marker on one or both of the anchor member and the tensioning

member. For example, a first radiopaque marker may be located near the proximal end portion when the anchor member is in the shortened configuration and a second radiopaque marker may be located near the distal end portion when the anchor member is in the shortened configuration. The distal end portion of the anchor member may include a relatively more rigid tip as compared to the anchor member and having a reduced width as compared to an adjacent portion of the anchor member. The anchor member itself may be designed in any of numerous manners, including designs that have a uniform width along the length thereof, and designs that have a varying width along the length. Other features may be incorporated such as edge portions that are slightly more rigid than a central area of the anchor member. Entire sections of the anchor member may be relatively rigid as compared to fold line portions thereof while still resulting in a generally flexible anchor member. As necessary, hinge portions, such as living hinges, may be designed into the anchor member to allow for folding or other shortening action of the anchor member. While a tensioning member is specifically disclosed herein for activation purposes (that is, activating the anchor member from the elongate configuration to the shortened configuration), the invention in various combinations may utilize other types of activation, such as compressive activation.

[0011] Each of the embodiments of the tissue anchor may be part of a catheter-based anchoring system having a delivery catheter and a suitable deploying device associated with the delivery catheter and operable to extend the anchor member from the delivery catheter. The deploying device may further comprise a deploying catheter at least partially containing the anchor member and at least partially contained within the delivery catheter.

[0012] The invention further provides for various methods of anchoring tissue as generally described herein. For example, in one aspect a method of anchoring tissue is provided comprising inserting a generally flexible elongate anchor member through the tissue, and pulling a first end of a tensioning member coupled for sliding movement relative to the first anchor member to draw the proximal and distal end portions toward each other and to compress the intermediate portion into the shortened configuration with at least one of the proximal and distal end portions engaged against the tissue.

[0013] In another aspect of the invention, a method of tissue anchoring is provided comprising inserting the generally flexible flat elongate strip having proximal and distal end portions through the tissue, and pulling a first end of a tensioning member operatively connected to the strip to draw the proximal and distal end portions of the strip toward each other into the shortened configuration engaged against the tissue.

[0014] In another aspect, a method of tissue anchoring is provided comprising inserting the generally flexible flat elongate strip having proximal and distal end portions through the tissue, and pulling a first end of a tensioning member operatively connected to the strip to configure at least a portion of the strip into a shortened configuration engaged against the tissue.

[0015] In each of the embodiments engagement of the anchor member against the tissue may be engagement against opposite sides of at least one tissue layer, or engagement against only one side of at least one tissue layer.

[0016] Additional features and advantages of the invention will become readily apparent to those of ordinary skill in the art upon review of the following

~~"detailed description of the illustrative embodiments taken in conjunction with the~~
accompanying illustrative figures.

Brief Description of the Drawings

[0017] Fig. 1 is a perspective view of a tissue anchor constructed in accordance with a first embodiment of the invention.

[0018] Fig. 2A is a side view of the tissue anchor shown in Fig. 1, with the tissue anchor deployed through a layer of tissue.

[0019] Fig. 2B is a side view similar to Fig. 2A, but illustrating the distal portion of the tissue anchor being moved toward the layer of tissue.

[0020] Fig. 2C is a side view similar to Fig. 2B, but showing the distal portion fully compressed and engaged against the layer of tissue.

[0021] Fig. 2D is a side view similar to Fig. 2C but illustrating the proximal portion of the tissue anchor being moved toward the layer of tissue.

[0022] Fig. 2E illustrates the proximal and distal portions of the tissue anchor fully compressed against opposite sides of the layer of tissue.

[0023] Fig. 2F is an enlarged cross sectional view illustrating the fully deployed and fastened anchor with a layer of tissue between proximal and distal anchor portions.

[0024] Fig. 3 is a side cross sectional view similar to Fig. 2F, but illustrating the fastening of two layers of tissue between the proximal and distal anchor portions.

[0025] Figs. 4A-4F are perspective views illustrating successive steps in an annuloplasty procedure on the mitral valve of a patient utilizing tissue anchors of the first embodiment.

[0026] Figs. 5A-5E are perspective views illustrating a mitral valve annuloplasty procedure utilizing tissue anchors constructed according to a second embodiment of the invention.

[0027] Fig. 6 is a side elevational view illustrating the tissue anchor constructed in accordance with the second embodiment.

[0028] Fig. 7 is a front view of the elongate strip portion of the anchor.

[0029] Fig. 7A is a front elevational view similar to Fig. 7, but illustrating one embodiment of radiopaque markers used on the elongate strip.

[0030] Fig. 7B is a front elevational view of an alternative anchor strip having a varying width along its length.

[0031] Fig. 7C is a side elevational view of another alternative anchor strip utilizing more rigid fold sections separated by living hinges.

[0032] Figs. 8A-8D are respective side views illustrating a sequence of steps used for securing the tissue anchor of the second embodiment to a layer of tissue.

[0033] Fig. 8E is a view similar to Fig. 8D, but illustrating an alternative tip and tensioning member arrangement.

[0034] Figs. 9A-9C are respective side elevational views illustrating an annuloplasty procedure in which two tissue anchors of the second embodiment are daisy-chained together with a single tensioning member to plicate the tissue between the anchors in a more integrated procedure.

[0035] Figs. 10A and 10B are respective side elevational views illustrating the tissue anchor of the second embodiment used to provide an anchor or securement location on only one side of a tissue layer.

Detailed Description of Illustrative Embodiments

[0036] Referring first to Fig. 1, a tissue anchor 10 constructed in accordance with a first embodiment of the invention generally includes a tensioning member 12, such as a suture, extending through spaced apart points along a flat elongate strip 14 of flexible material, such as a surgical grade fabric. It will be appreciated that the tensioning member 12 may take other forms other than suture material, such as cable or any other small diameter member having a high enough tensile strength for the intended anchoring use. The elongate strip 14 may also take various forms such as woven or nonwoven fabrics, polymers, metals or other suitable materials or combinations of materials. One or more separate pledgets or other securement members (not shown) may be used in conjunction with the elongate strip 14 for added securement and/or concealing the elongate strip 14 and, for example, thereby inhibiting blood clotting within or adjacent to the folds that will be formed in the strip 14.

[0037] A woven or nonwoven material may contain additional materials, such as threads, beads or other elements that cause at least portions of the strip 14 to be radiopaque. Currently, a surgical grade fabric constructed from polyester, such as Dacron®, is contemplated for use in constructing the strip 14. One of many possible alternative materials for use in constructing strip 14 is polytetrafluoroethylene (PTFE). Tissue anchor 10 may be partly or wholly formed from materials that are absorbed into the patient's tissue over time, depending on the intended use. The edges and/or other portions of the strip 14 may be suitably modified to prevent fraying, such as by being coated with a material that locks the fibers in place, or otherwise modified in a manner that locks the fibers at least at the edges of the strip 14 in place.

[0038] The suture 12 may extend from a proximal end portion 14a of the fabric strip 14 to a distal end portion 14b and then loop back through spaced apart points of the fabric strip 14 to the proximal end portion 14a where a knot 16 or other stop member is located for reasons to be described below. As will become apparent, the suture 12 extends through spaced apart locations along the elongate strip 14 such that tensioning of the suture 12 or other tensioning member will cause the elongate strip 14 to form folded portions 14c when the tensioning member 12 is placed under tension or pulled. Thus, the elongate strip 14 is activated in this manner between essentially an elongate deployment orientation or configuration, such as shown in Fig. 1, and a shortened configuration, such as a folded or otherwise shortened configuration having an expanded width in at least one dimension as compared to the elongate deployment configuration. It will be appreciated that the deployment orientation may take on various forms due to the flexible nature of the strip 14, especially when using a highly flexible fabric or other material. For example, a fabric material or other similarly flexible materials may be folded or otherwise deformed for carrying purposes within a catheter and/or during deployment to a tissue site and then suitably activated at the tissue site.

[0039] More specifically referring to Figs. 2A-2E, the elongate strip 14 and attached suture 12 are initially inserted through at least one tissue layer 20 as generally shown in Fig. 2A. One end or portion 12a of the suture 12 is then pulled and thereby placed under tension. It will be appreciated that, for catheter-based procedures, suture portion 12a may extend to a location outside the patient's body for pulling or tensioning, or it may be grasped by a suitable mechanism within the catheter and pulled or tensioned. Pulling suture portion 12a may initially draw the distal portion 14b of the elongate strip 14 toward the

layer of tissue 20 as shown in Fig. 2B. Once the distal portion 14b is compressed against the layer of tissue 20, the proximal portion 14a begins to be drawn and compressed against a proximal side of the tissue 20 as shown in Figs. 2C-2E. This occurs because end 12a of the suture 12 is being pulled downwardly (as viewed for purposes of discussion in Figs. 2C-2E) and, since the suture 12 is looped in a reverse direction through distal end portion 14b of the elongate strip 14, the knot 16 at the end of the suture 12 moves upwardly and brings the proximal portion 14a of the elongate strip 14 with it. In this manner, the proximal portion 14a of the elongate strip 14 is being folded and drawn along the suture 12 toward the layer of tissue 20 and then firmly compressed against the proximal side of the layer of tissue 20 as shown in Fig. 2E. As further shown in Fig. 2F, a suitable locker element, such as a crimp member 22, a knot or other element may be used to maintain the suture 12 and elongate strip 14 in the positions shown in Fig. 2F securely anchoring the proximal and distal portions 14a, 14b of the elongate strip 14 folded against opposite sides of the tissue 20.

[0040] As further shown in Fig. 3, the same general procedure may be used to secure two distinct tissue layers 30, 32 together by initialing extending the elongate strip 14 and tensioning member 12 through at least two layers of tissue 30, 32. In this manner, for example, two layers of tissue 30, 32 may be securely fastened together. This may, for example, involve two entirely different layers and even types of tissue or the same layer of tissue which has been folded over to effectively form two layers (i.e., portions) of tissue.

[0041] Figs. 4A-4E schematically illustrate an annuloplasty procedure performed on a mitral valve 40 of a heart 42 utilizing tissue anchors 10 as described above in regard to the first embodiment. Performance of the

annuloplasty procedure may have many variations, but is generally illustrated by the placement of at least two tissue anchors 10 and securement of the two anchors 10 together, such as with one or more tensioning members 12 therebetween. For an additional illustrative description of catheter-based annuloplasty procedures that may utilize any of the tissue anchors within the scope of the present invention, reference may be made to U.S. Patent Application Serial No. 10/948,922, filed on September 24, 2004, assigned to the assignee of the present invention, and the disclosure of which is hereby entirely incorporated by reference herein.

[0042] As illustrated in Fig. 4A, a first tissue anchor 10 is deployed through a catheter device 50 which may, for example, have an inner tubular member 52 or deploying catheter received within an outer tubular member 54 or delivery catheter. The tissue anchor 10 and tensioning member 12 are carried within the inner tubular member 52 and are deployed from a distal end 52a thereof. To ensure that proper force is applied to penetrate the tissue, tissue anchor 10 may be deployed or extended after the inner tubular member 52 has been inserted through tissue at the annulus 40a of the mitral valve 40. This is best illustrated in Fig. 4B. The inner tubular member 52 is withdrawn from the annulus tissue 40a either before, during or after activation of the distal end portion 14b of the elongate strip 14. As previously described, activating (e.g., compression, folding or otherwise shortening) the elongate strip 14 by pulling the suture 12 causes the distal end portion 14b and then proximal end portion 14a to be securely compressed and folded against opposite sides of the annulus tissue 40a. This procedure is repeated at least one additional time to securely fasten an additional tissue anchor 10 at a location spaced from the initial location. For example, the initial location may be at location P2 of the

Mitral valve annulus 40 while the second location may be spaced on either side of location P2. Catheter device 50 may be inserted into the location of annulus 40a in various manners, but is shown being inserted downwardly through the aortic valve 53 into the left ventricle 55, and curving upward toward the mitral valve annulus 40a.

[0043] In the illustrative example shown in Fig. 4E, three tissue anchors 10 have been deployed and securely fastened to the annulus tissue 40a. As shown in Fig. 4F a suture locker 56 may then be deployed and used to maintain relative position and, therefore, tension between each of three respective tensioning members or sutures 12 associated with the three tissue anchors 10 after the tissue anchors 10 have been pulled closer to each other thereby plicating the tissue 40a between the anchors 10. This essentially shortens the valve annulus 40a and pulls the posterior leaflet 60 toward the anterior leaflet 62 to prevent leakage through the valve 40, i.e., to achieve better coaptation of the posterior and anterior leaflets 60, 62 during systole.

[0044] Figs. 5A-5E illustrate a similar annuloplasty procedure on a mitral valve 40 utilizing a second embodiment of a tissue anchor 70 and a modified method of deployment and activation. In general, the differences between anchor 70 and anchor 10 will be described below with the understanding that all other attributes, options and features associated with anchor 70 may be as described above in connection with anchor 10. As shown in Fig. 5A, in this embodiment a tensioning member 72 is again used to activate a flexible, elongate flat strip 74 having proximal and distal end portions 74a, 74b. Strip 74 includes a tip 76 that is formed or otherwise secured on the distal end portion 74b. The tensioning member 72 and the tip 76 are arranged such that the tensioning member 72 slides relative to the tip 76. More particularly, the

tensioning member 72 can be threaded through the tip 76. Tip 76 is made to be relatively rigid as compared to other flexible portions of strip 74 and of smaller diameter than the width of strip 74. Therefore, tip 76 helps to penetrate the annulus tissue 40a as the inner tubular member 52 and the elongate strip 74 are extended through the tissue 40a. A wire 73 may be used to push the tip 76 out of the tubular member 52 at the desired time. The tip 76 may protrude slightly from the inner tubular member 52 as the tissue 40a is penetrated to assist with piercing the tissue 40a. The tip 76 may also assist with forcing distal portion or half 74b of strip 74 into a folded or otherwise shortened configuration. To help prevent the distal portion 74b of the elongate strip from pulling back through the tissue 40a as the inner tubular member 52 is withdrawn from the annulus tissue 40a, the free end of the tensioning member 72 is pulled while the inner tubular member 52 is still penetrated through the tissue 40a and into the left atrium 80 from the left ventricle 55. This forms the distal portion 74b into a folded or otherwise shortened configuration as shown in Fig. 5B. The inner tubular member 52 may then be withdrawn without also withdrawing the elongate flexible strip 74 with it, as shown in Fig. 5C. The proximal portion 74a of the elongate strip 74 is then deployed by pulling the inner tubular member 52 further in a proximal direction, and thereby exposing the full length of strip 74. The tensioning member 72 is pulled or tensioned so as to draw and compress the proximal portion 74a of the elongate strip 74 into a folded, shortened condition against an underside of the annulus tissue 40a as shown in Fig. 5D. As with the previously described annuloplasty procedure using the first embodiment of the tissue anchor 10, this is repeated as many times as necessary to create the necessary number of tissue plications. Fig. 5E illustrates this by way of an exemplary view of three successive tissue anchor

Securement locations with tissue anchors 70 that may be drawn together and locked in place to achieve and retain the plications as described in connection with Fig. 4F. Such plications reduce or close the gap between the posterior and anterior leaflets 60, 62. during systole

[0045] Fig. 6 is a side elevational view of the tissue anchor 70 as shown and described with respect to the annuloplasty procedure of Figs. 5A-5E. This embodiment differs from the first embodiment in a number of different manners, in addition to the use of a distal tip 76 for tissue penetration purposes. For example, the elongate strip 74 is somewhat shorter than the elongate strip 14 utilized in the first embodiment. For example, the strip 74 may be about 40 mm long by about 3 mm wide. Of course, any other desired dimensions and shapes may be used depending on application needs. This may be desirable to achieve a lower profile deployed and fastened configuration with fewer folds that may lead to more versatile applications, lower incidents of blood clotting, easier use, etc. In addition, respective proximal and distal radiopaque bands 90, 92 are secured to the suture 72 at the proximal end portion of the strip 74 and to either the interior or exterior of the distal tip 76. Under a fluoroscope, these bands or other markers 90, 92 will indicate to the surgeon that the anchor 70 has been deployed, activated and fully compressed and/or fastened as necessary during the procedure. The tip 76 itself may alternatively be formed from a radiopaque material. In this second embodiment, the knot 94 formed in the suture 72 or other tensioning member is a slip knot through which another portion of the suture 72 slides during activation of the tissue anchor 70. It will be appreciated that this slip knot 94 may be replaced by another element which serves essentially the same purpose but takes the form, for example, of a small tubular element or other feature similar in function to a slip knot.

[0046] As further shown in Figs. 6 and 7, the tensioning member or suture 72 can advantageously extend through respective fold portions 74c of the elongate strip 74 in essentially an hourglass configuration. Specifically, adjacent portions of the suture 72 located near the proximal and distal end portions 74a, 74b of the strip 74 are spaced farther apart than the adjacent portions of the suture 72 in the middle of the strip 74. As further shown in Fig. 7A, radiopaque markers, such as distinct areas of dots 95, may be used for enabling the surgeon to visualize the folds of the elongate strip 74 during deployment and securement of the elongate strip 74. These dots or other radiopaque markers may be printed on the strip 74. For example, dots 95 or other markers may be formed with a platinum powder base ink or other suitable material that is radiopaque and biologically compatible. This radiopaque material may also add stiffness to the fold sections 74c thereby helping to maintain the fold sections 74c flat and increasing retention force on the tissue. Meanwhile, the fold lines 74d between fold sections 74c can remain highly flexible to create tight radius fold lines. As further shown in Fig. 7, each of the holes 96 that the tensioning member or suture 72 is received through may be marked by circles 98 surrounding each hole 96 or other markers for visualizing purposes during assembly of the tensioning member or suture 72 with the elongate strip 74. Optionally, holes 96 may be eliminated and the suture 72 may be threaded with a needle through the strip 74. One could also, for example, choose different sets of holes 96 along strip 74 for receiving the tensioning member or suture 72 thereby changing the width of the folds and/or number of folds and/or shape of the folds depending on the application needs or desires of the surgeon. The tensioning member or suture 72 may be threaded or otherwise attached along the strip 74 in any number of manners

Including, for example, x-patterns or other crossing patterns, zig-zag patterns, etc. that may alter the folded or otherwise shortened or compressed footprint of the anchor into various beneficial shapes, such as flower shapes, circular shapes or other rounded shapes, ball shapes or other configurations.

Modifications of the manner in which the tensioning member or suture 72 is threaded or otherwise attached along the length of strip 74 may result in higher or lower tensioning force being required to compress the anchor and/or higher or lower friction holding force that may help maintain the anchor in the compressed or shortened configuration. The width of the elongate strip 74' may be varied along its length, such as by tapering, stepping, or forming an hourglass shape or shapes along the length of the strip 14. For example, as illustrated in Fig. 7B, having proximal and distal end portions 75, 77 of wider dimension than an intermediate or middle portion or portions 79 along the length of strip 74' will allow these wider portions 75, 77 may cover over the more intermediate folded portions 79 and prevent unnecessary contact with adjacent tissue during use. It will be appreciated that like reference numerals are used herein to refer to like elements in all embodiments and reference numerals with prime marks (') or double prime marks (") refer to like elements that have been modified in a manner as described herein or otherwise shown in the associated figure. Strip 74 may have variable stiffness including, for example, a relatively rigid perimeter or relatively rigid edges 74e, 74f (Fig. 7) or intermittent relatively rigid sections 74c" separated by flexible sections such as living hinges 74d" (Fig. 7C) that may aid in folding and securing the elongate strip 74" into a folded condition.

[0047] Figs. 8A-8D illustrate a series of steps for deploying and securely fastening the tissue anchor 70 of the second embodiment to a layer of tissue

100. Generally, as shown in Fig. 8A, the combination of the elongate strip 74 and tensioning member or suture 72 is deployed through the layer of tissue 100. One end or portion 72a of the suture 72 that extends through the slip knot 94 is then pulled. This causes the distal portion 74b of the elongate strip 74 to fold and compress against the distal side of the tissue layer 100. As shown in Fig. 8B, further pulling of the tensioning member 72 causes the slip knot 94 to ride upwardly or distally along the suture 72 and against a proximal portion 74a of the elongate strip 74 thereby folding and compressing the proximal portion 74a against the proximal side of the tissue layer 100 as shown in Fig. 8C. As shown in Fig. 8D, a suitable crimp or locking element 102 may be used to securely lock the slip knot 94 in place relative to the suture or tensioning member segment which extends therethrough. This will lock the entire anchor 70 in place with the respective proximal and distal folded strip portions 74a, 74b securely retaining the tissue layer or layers 100 therebetween. Fig. 8D shows the tip 76 acting as a retainer on top of the distal end portion 74b to assist in holding the distal end portion 74b in place. Fig. 8E shows an alternative in which the tensioning member is threaded through at least one hole 76a more centrally located in the tip. Yet another alternative would be to thread the tensioning member through two centrally located holes instead of through the proximal end of the tip 76 and one centrally located hole 76a as shown in Fig. 8E. These alternatives allow the tip 76 to act more like a "T"-bar with forces acting in a more perpendicular or normal manner relative to the distal end portion 74b of the strip 74.

[0048] Figs. 9A-9C illustrate another alternative embodiment of a plication procedure, for example, for use during annuloplasty on a mitral valve annulus 40a. In this regard, a single tensioning member, such as a suture 103 or other

member may be used to deploy, fasten and draw together at least two separate tissue anchors 110. As shown in Fig. 9A, first and second tissue anchors 110 may be respectively deployed at spaced apart locations along the mitral valve annulus 40a. Each tissue anchor 110 includes an elongate strip 114 of flexible material, such as fabric or other material as described above, as well as a single suture 103 or tensioning member extending through each of the elongate strips 114. Upon deployment of the two tissue anchors 110 through the tissue layer 40 at spaced apart locations, the free end of the suture 103 or tensioning member is pulled thereby securely fastening the first tissue anchor 110 as shown in Figs. 9A and 9B and subsequently securely fastening the second tissue anchor 110 to the annulus tissue 40a. Upon further pulling or tensioning of the suture 103, the tissue anchors 110 will be drawn together to plicate the tissue 40 therebetween as shown in Fig. 9C. A crimp or other locker member 116 may then be used to lock in the desired amount of plication by crimping onto the free end of the suture 103 adjacent to the slip knot 94 of the first tissue anchor 110 as shown in Fig. 9C. The free end of the suture 103 may then be cut to eliminate or reduce the length of the suture tail.

[0049] Figs. 10A and 10B illustrate a tissue anchor 70 of the second embodiment, for example, being used to provide an anchor or securement location on only one side of a tissue layer 120. In this regard, the tissue anchor 70 may be extended entirely through the tissue layer(s) 120. The free end of the suture or tensioning member 72 is then pulled proximally to compress and fold the elongate strip 74 against the distal side of the tissue layer 120 as shown in Fig. 10B. It will be appreciated that activation of strip 74 occurs similarly to the other described embodiments, except that the activated portion (that is, the folded or otherwise shortened portion) is located entirely on one

side of the tissue layer 120. As illustrated, the intermediate or middle portion between the proximal and distal end portions of the anchor member shortens to adjust to the amount of tissue contained therebetween (if any) or shortens during the compression process on only one side of the tissue.

[0050] While the present invention has been illustrated by a description of various illustrative embodiments and while these embodiments have been described in some detail, it is not the intention of the Applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features of the invention may be used alone or in numerous combinations depending on the needs and preferences of the user.

WHAT IS CLAIMED IS:

1. A tissue anchor comprising:

a generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion, and

a tensioning member operatively connected to said anchor member such that said anchor member can slide relative to said tensioning member, said tensioning member capable of being pulled to cause said anchor member to move relative to said tensioning member from said elongate configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the tissue between the proximal and distal end portions.

2. The tissue anchor of claim 1, wherein said generally flexible anchor member is formed from a material selected from at least one of: natural fibers, synthetic fibers, polymers, and metals.

3. The tissue anchor of claim 2, wherein said tensioning member further comprises a suture.

4. The tissue anchor of claim 1, wherein said tensioning member further comprises a suture.

6. The tissue anchor of claim 1, wherein said tensioning member includes a stop member engageable with said anchor member.
6. The tissue anchor of claim 5, wherein said stop member further comprises a knot in said tensioning member.
7. The tissue anchor of claim 1, wherein said tensioning member extends through said anchor member at multiple locations between the proximal end portion and the distal end portion.
8. The tissue anchor of claim 1, wherein said anchor member and said tensioning member are configured such that said anchor member forms at least one fold upon pulling said first end of said tensioning member.
9. The tissue anchor of claim 1, further comprising a lock member engageable with said tensioning member to retain said anchor member in the shortened configuration.
10. The tissue anchor of claim 1, further comprising at least one radiopaque marker on at least one of said anchor member and said tensioning member.

11. The tissue anchor of claim 10, further comprising a first radiopaque marker located proximate said proximal end portion when said anchor member is in the shortened configuration and a second radiopaque marker located proximate said distal end portion when said anchor member is in the shortened configuration.

12. The tissue anchor of claim 1, wherein said distal end portion includes a relatively rigid tip, said tip being of reduced width relative to an adjacent portion of said anchor member.

13. The tissue anchor of claim 12, wherein said tip acts as a compressive force applying member against the distal end portion of the anchor member when the anchor member is in the shortened configuration.

14. The tissue anchor of claim 1, wherein said anchor member varies in width along its length when in the elongate configuration.

15. The tissue anchor of claim 1, wherein said anchor member includes an edge portion that is more rigid than a central area of said anchor member.

16. A tissue anchor comprising:

a flat, generally flexible anchor member capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue, and

a tensioning member operatively connected to said anchor member such that said anchor member can slide relative to said tensioning member, said tensioning member capable of being pulled to cause said anchor member to move relative to said tensioning member from said elongate configuration to said shortened configuration.

17. A tissue anchor comprising:

a flat anchor member formed from a strip of fabric material and capable of movement between an elongate configuration suitable for deployment and a shortened configuration suitable for anchoring against tissue,

a tensioning member operatively connected to said anchor member such that said anchor member can slide relative to said tensioning member, said tensioning member capable of being pulled to cause said anchor member to move relative to said tensioning member from said elongate configuration to said shortened configuration, and

a lock member capable of securing the anchor member in the shortened configuration.

18. A tissue anchor comprising:

a flat, generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration suitable for deployment through a catheter and a shortened configuration suitable for anchoring against the tissue, and

a tensioning member operatively connected to said anchor member such that said anchor member can slide relative to said tensioning member, said tensioning member capable of being pulled to cause said anchor member to move relative to said tensioning member from said elongate configuration to said shortened configuration against the tissue.

19. A tissue anchor comprising:

a flat elongate strip formed from a generally flexible material and having proximal and distal end portions,

a tensioning member having first and second ends, said tensioning member operatively connected to said elongate strip such that pulling on said first end of said tensioning member causes said proximal and distal end portions of said elongate strip to move toward each other into a shortened configuration suitable for anchoring against the tissue.

20. A tissue anchor comprising:

a generally flexible flat anchor strip capable of being inserted through tissue in an elongate configuration and movable to a shortened, folded configuration suitable for anchoring against at least one side of the tissue,

an activation member operatively connected to said anchor strip and operable to move the anchor strip from the elongate configuration to the shortened, folded configuration.

21. The tissue anchor of claim 20, wherein the shortened, folded configuration further comprises a zig-zag fold pattern.

22. A tissue anchoring system, comprising:

a delivery catheter,

a generally flexible anchor member capable of being inserted through tissue and moving between an elongate configuration and a shortened configuration suitable for anchoring against at least one side of the tissue, said anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion between said proximal end portion and said distal end portion, and

a deploying device operatively associated with said delivery catheter and operable to extend the anchor member from said delivery catheter, and

a tensioning member operatively connected to said anchor member such that said anchor member can slide relative to said tensioning member, said tensioning member capable of being pulled to cause said anchor member to move relative to said tensioning member from said elongate

configuration to said shortened configuration wherein the compressible intermediate portion can compress and thereby adjust to the thickness of the layer of tissue between the proximal and distal end portions.

23. The system of claim 22, wherein said deploying device further comprises a deploying catheter at least partially containing said anchor member and at least partially contained within said delivery catheter.

24. The system of claim 22, wherein said anchor member is formed from a material selected from at least one of: natural fibers, synthetic fibers, polymers, and metals.

25. The system of claim 24, wherein said tensioning member further comprises a suture.

26. The system of claim 22, wherein said tensioning member further comprises a suture.

27. The system of claim 22, wherein said tensioning member includes a stop member engageable with said anchor member.

28. The system of claim 27, wherein said stop member further comprises a knot in said tensioning member.

29. The system of claim 22, wherein said tensioning member extends through said anchor member at multiple locations between the proximal end portion and the distal end portion.

30. The system of claim 22, wherein said anchor member and said tensioning member are configured such that said anchor member forms at least one fold upon pulling said first end of said tensioning member.

31. The system of claim 22, further comprising a lock member engageable with said tensioning member to retain said anchor member in the shortened configuration.

32. The system of claim 22, further comprising at least one radiopaque marker on at least one of said anchor member and said tensioning member.

33. The system of claim 32, further comprising a first radiopaque marker located proximate said proximal end portion when said anchor member is in the shortened configuration and a second radiopaque marker located proximate said distal end portion when said anchor member is in the shortened configuration.

34. The system of claim 22, wherein said distal end portion includes a relatively rigid tip, said tip being of reduced width relative to an adjacent portion of said anchor member.

35. The system of claim 34, wherein said tip acts as a compressive force applying member against the distal end portion of the anchor member when the anchor member is in the shortened configuration.
36. The system of claim 22, wherein said anchor member varies in width along its length when in the elongate configuration.
37. The system of claim 22, wherein said anchor member includes an edge portion that is more rigid than a central area of said anchor member.
38. A method of anchoring tissue with a first generally flexible elongate anchor member having a proximal end portion, a distal end portion, and a compressible intermediate portion located between the proximal and distal end portions and movable between an elongated configuration and a shortened configuration, the method comprising:
- inserting the first generally flexible elongate anchor member through the tissue, and
 - pulling a first end of a tensioning member coupled for sliding movement relative to the first anchor member to draw the proximal and distal end portions toward each other and to compress the intermediate portion into the shortened configuration with at least one of the proximal and distal end portions engaged against the tissue.
39. The method of claim 38, wherein the tissue comprises a single layer of tissue.

40. The method of claim 38, wherein the tissue comprises at least two discrete tissue portions and the method further comprises connecting the two tissue portions together between the proximal and distal end portions of the first anchor member.

41. The method of claim 38, further comprising:
engaging the first anchor member against only one side of the tissue.

42. The method of claim 38, further comprising:
engaging the first anchor against opposite sides of the tissue.

43. The method of claim 38, further comprising:
inserting a second generally flexible elongate anchor member through the tissue at a location spaced from the first anchor member,
engaging the second anchor member against the tissue,
drawing the first and second members toward each other to plicate the tissue between the first and second anchor members, and
locking the first and second anchor members in position relative to each other with the tissue pliated therebetween.

44. The method of claim 43, wherein the tissue comprises annulus tissue of the mitral valve and drawing the first and second anchor members toward each other pliicates annulus tissue between the first and second anchor members.

45. The method of claim 38, wherein pulling the first end of the tensioning member forms at least one fold in the first anchor member.

46. The method of claim 38, wherein pulling the first end of the tensioning member forms multiple folds along the anchor member.

47. A method of tissue anchoring comprising:
inserting a first generally flexible flat elongate strip having proximal and distal end portions through the tissue, and
pulling a first end of a tensioning member operatively connected to the first strip to draw the proximal and distal end portions of the first strip toward each other into a shortened configuration engaged against the tissue.

48. The method of claim 47, wherein the tissue comprises a single layer of tissue.

49. The method of claim 47, wherein the tissue comprises at least two discrete tissue portions and the method further comprises connecting the two tissue portions together between the first and second ends of the first strip.

50. The method of claim 47, further comprising:
engaging the first strip against only one side of the tissue.

51. The method of claim 47, further comprising:
engaging the first strip against opposite sides of the tissue.

52. The method of claim 47, further comprising:

inserting a second generally flexible flat elongate strip having first and second ends through the tissue at a location spaced from the first strip,

pulling a first end of a second tensioning member operatively connected to the second strip to draw the first and second ends of the second strip toward each other into a shortened configuration engaged against the tissue,

tensioning the first and second tensioning members to draw the first and second strips toward each other to plicate the tissue between the first and second strips, and

locking the first and second tensioning members to each other.

53. The method of claim 52, wherein the tissue comprises annulus tissue of the mitral valve and drawing the first and second strips toward each other plicates annulus tissue between the first and second strips.

54. The method of claim 47, further comprising:

inserting a second generally flexible flat elongate strip having first and second ends through the tissue at a location spaced from the first strip,

drawing the first and second ends of the second strip toward each other into a shortened configuration engaged against the tissue,

drawing the first and second strips toward each other to plicate the tissue between the first and second strips, and

locking the first and second strips in position relative to each other.

55. II

A method of tissue anchoring comprising:

inserting a first generally flexible flat elongate strip having proximal and distal end portions through the tissue, and
pulling a first end of a tensioning member operatively connected to the first strip to configure at least a portion of the strip into a shortened configuration engaged against the tissue.

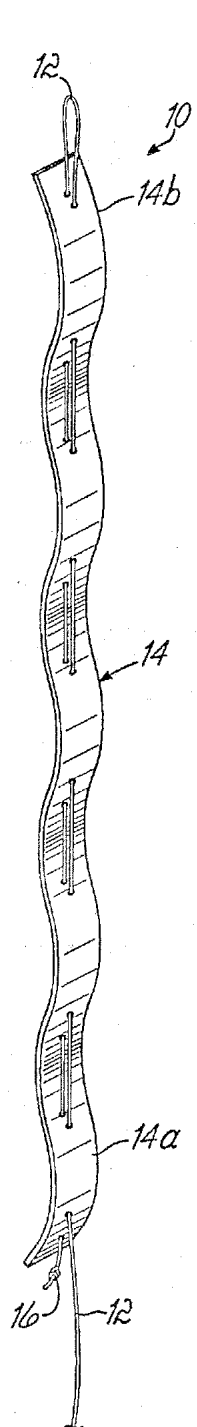


FIG. 1

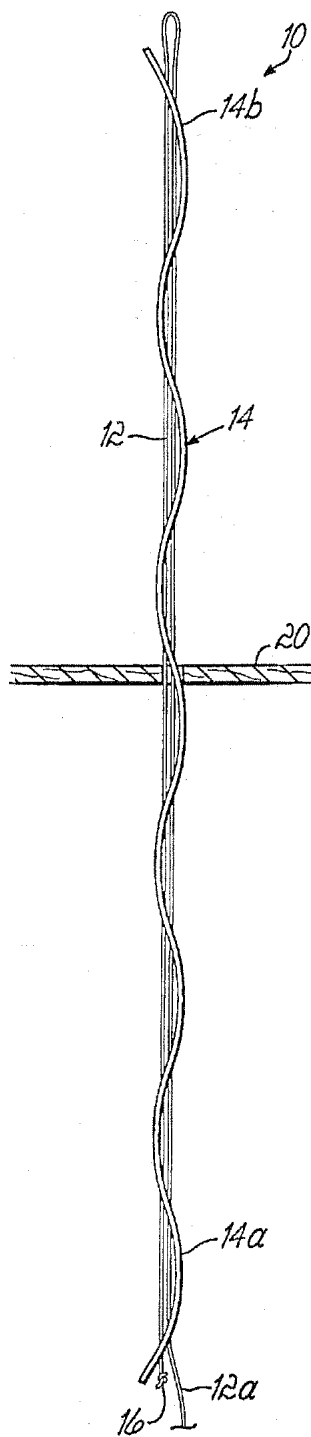


FIG. 2A

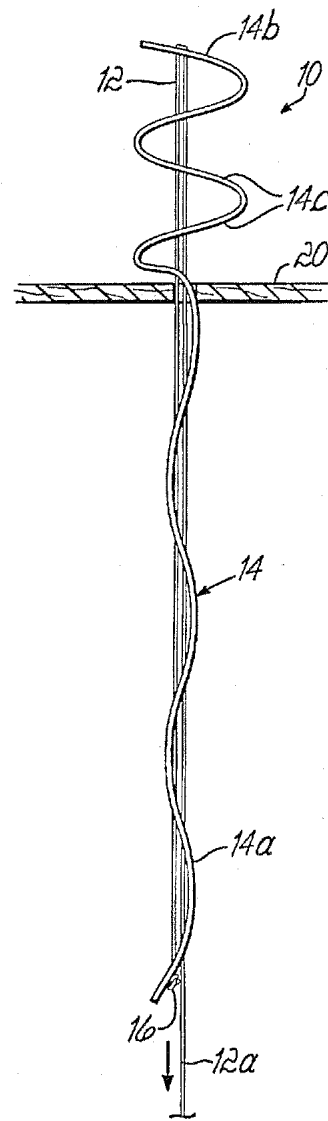


FIG. 2B

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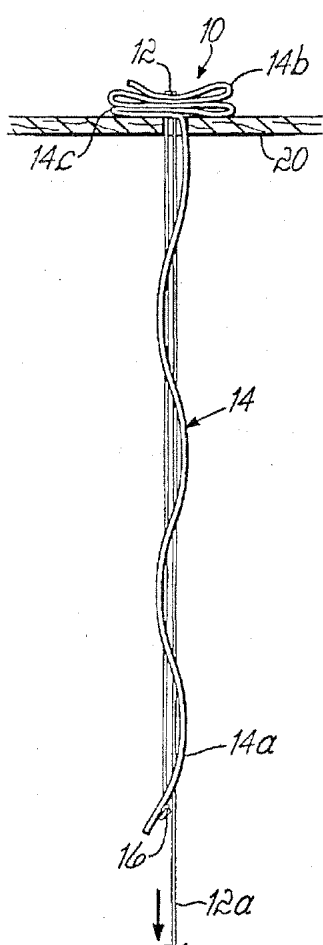


FIG. 2C

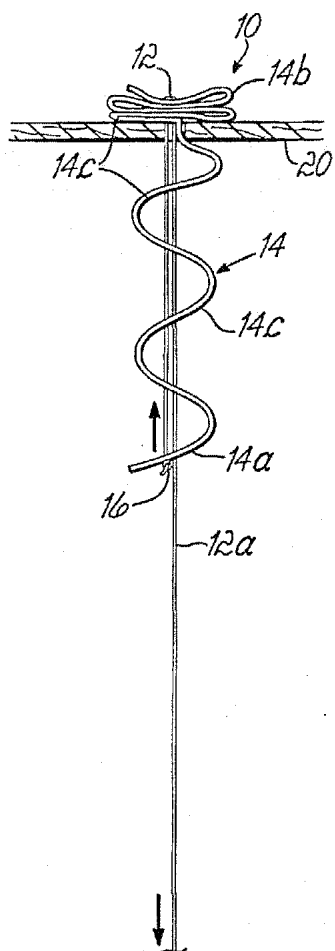


FIG. 2D

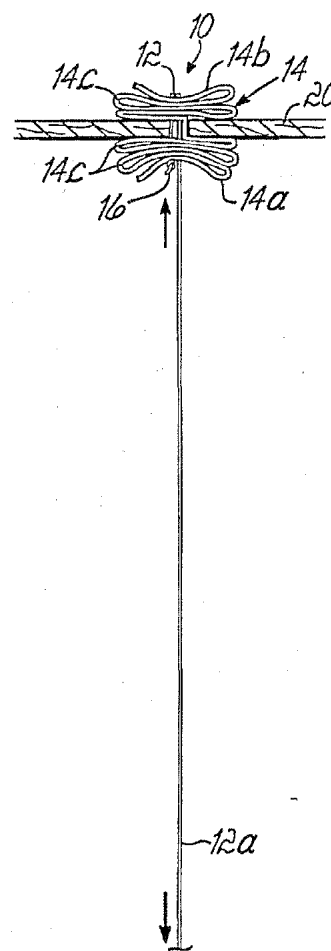


FIG. 2E

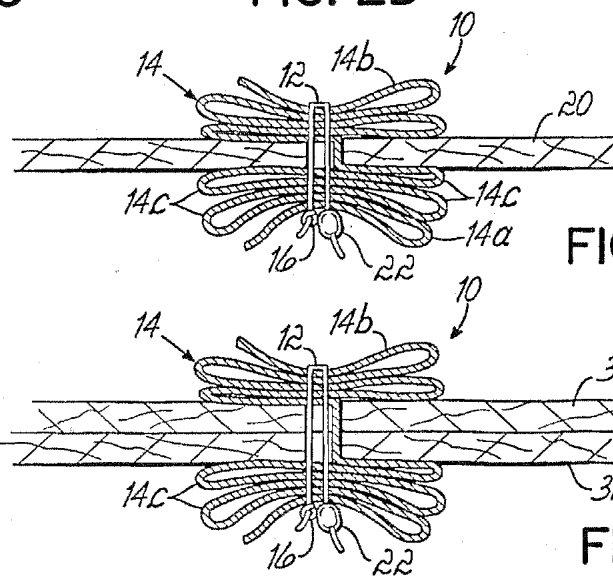


FIG. 2F

FIG. 3

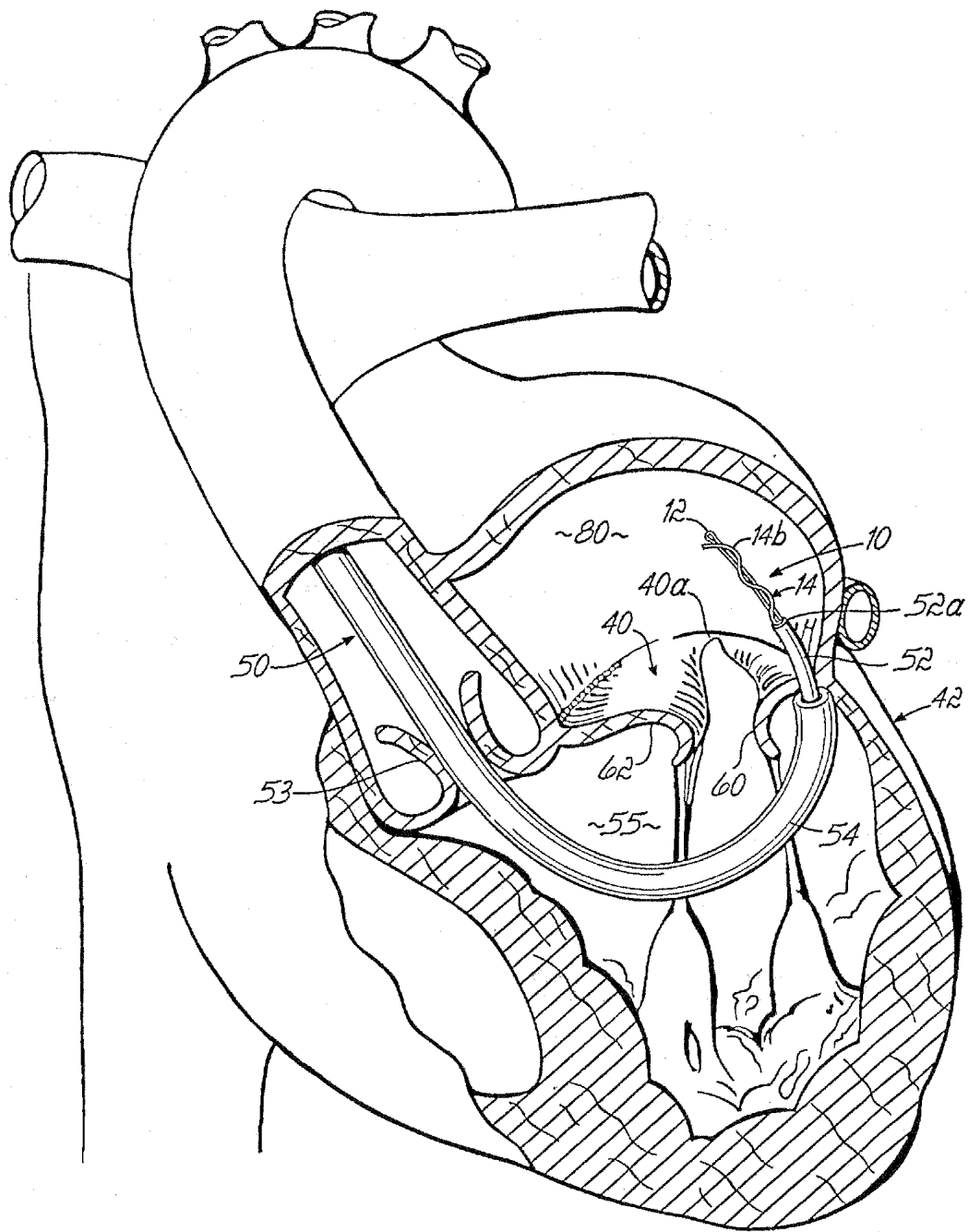


FIG. 4A

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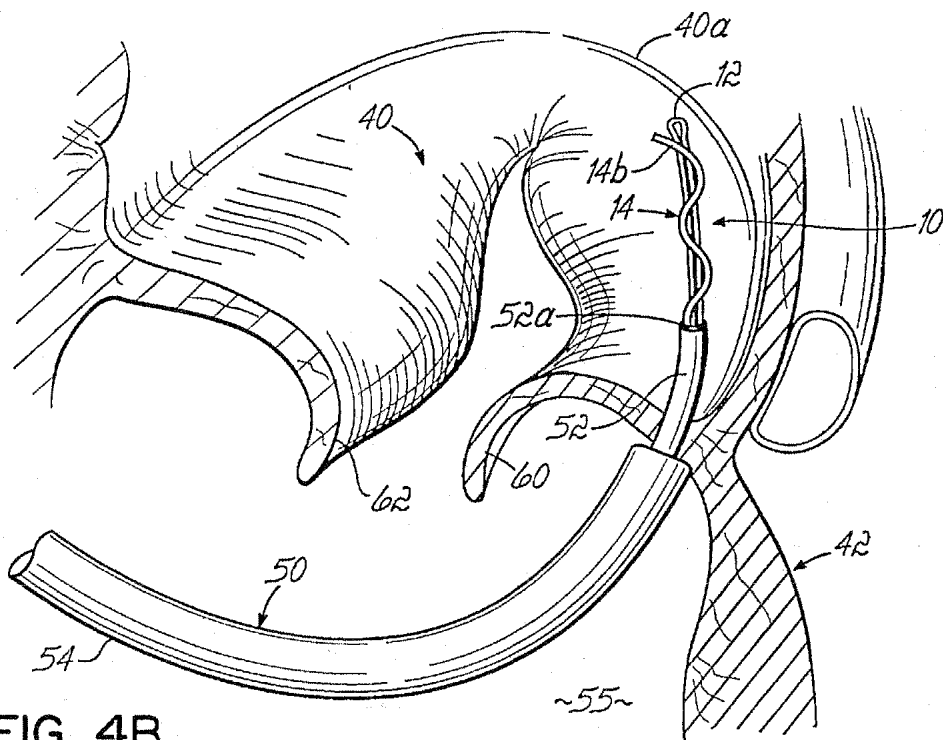


FIG. 4B

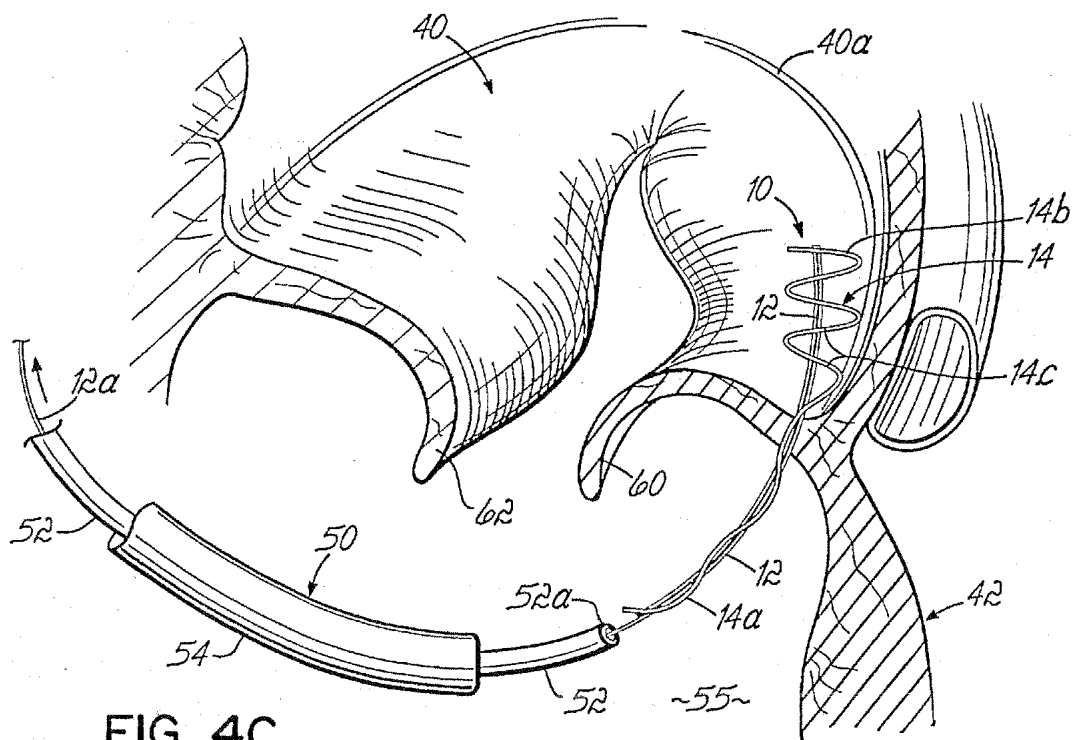


FIG. 4C

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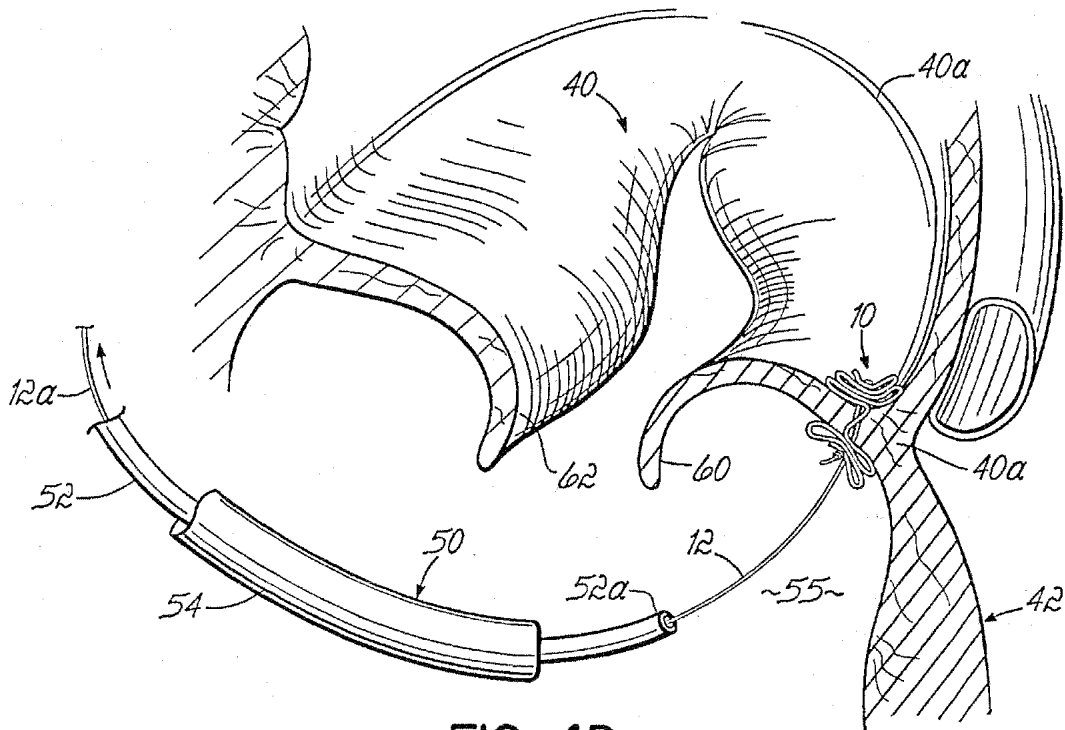


FIG. 4D

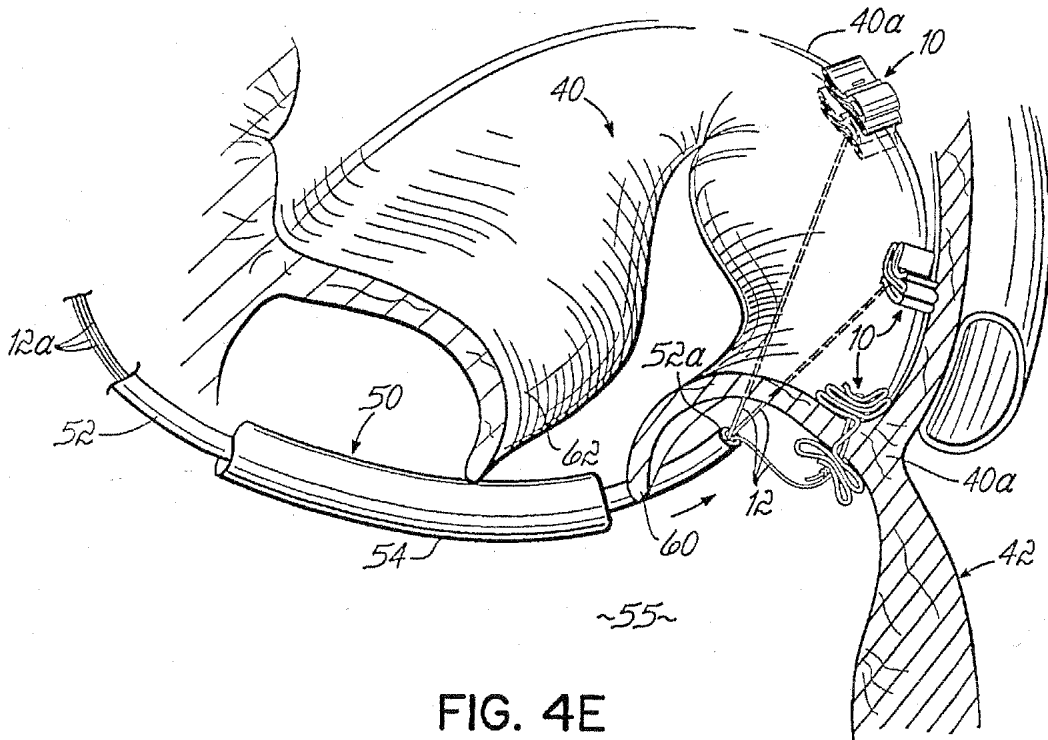


FIG. 4E

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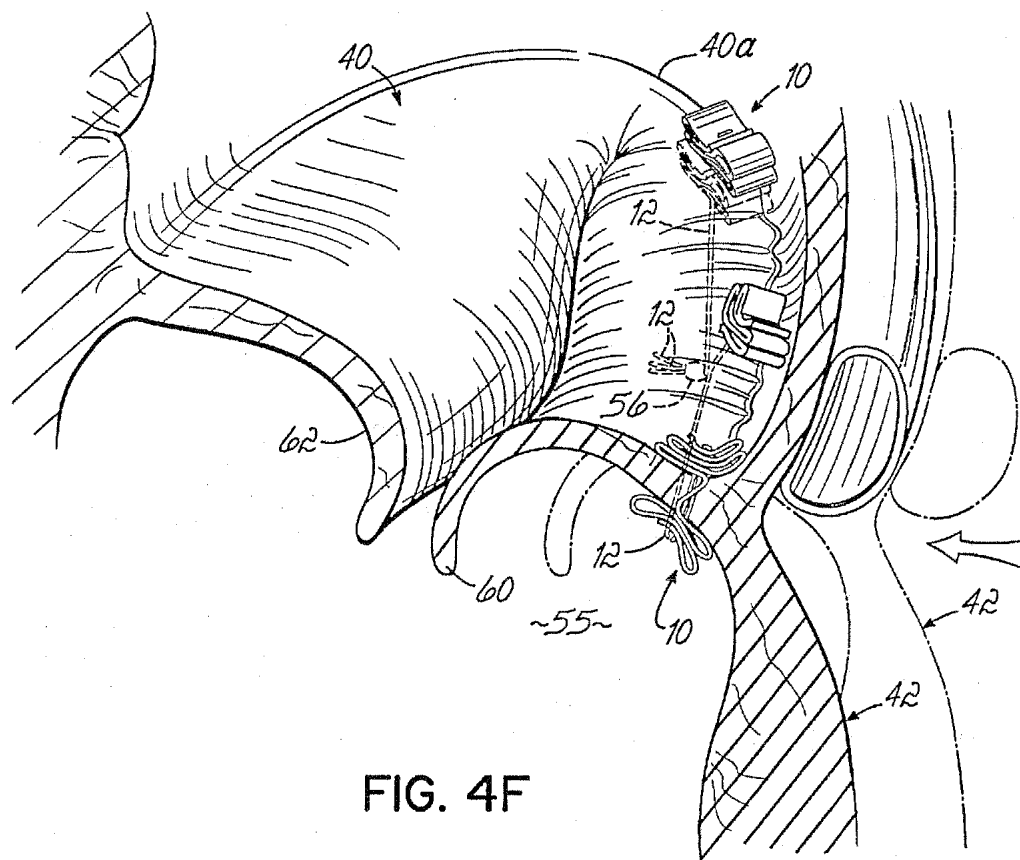


FIG. 4F

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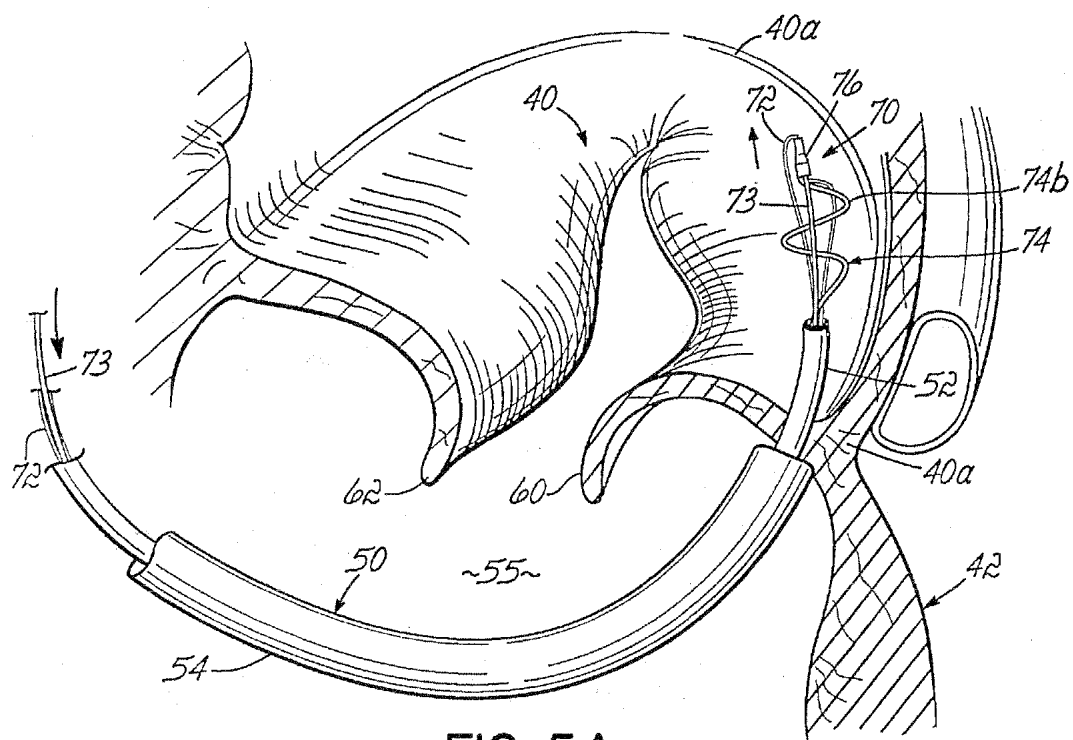


FIG. 5A

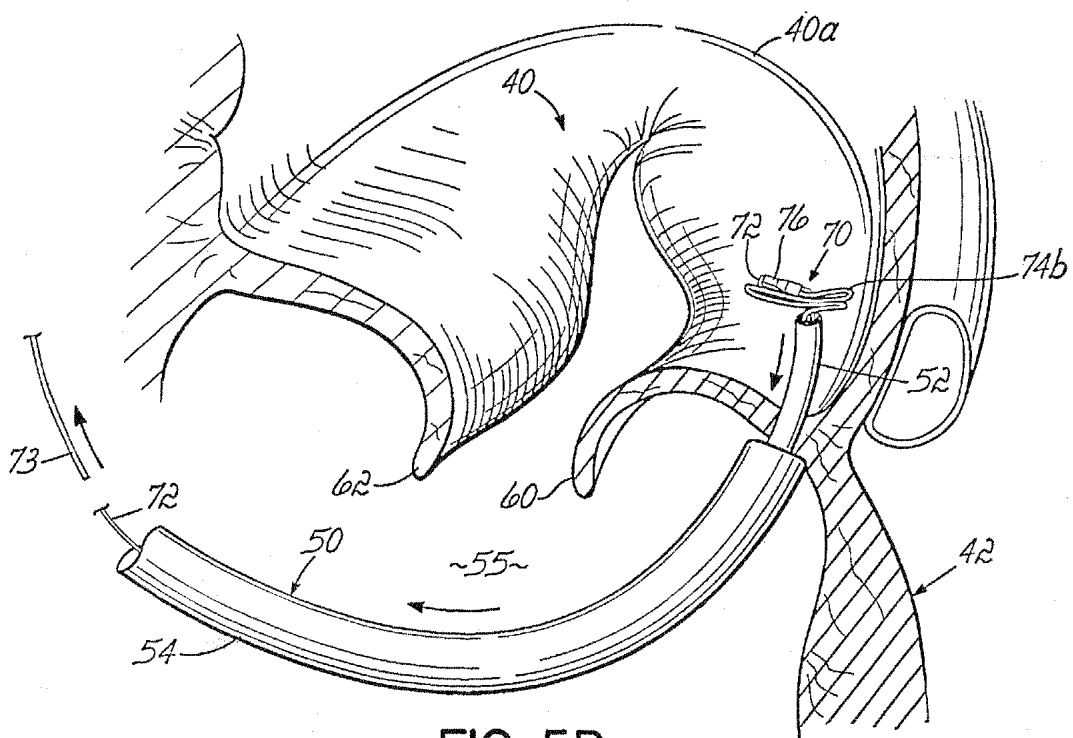


FIG. 5B

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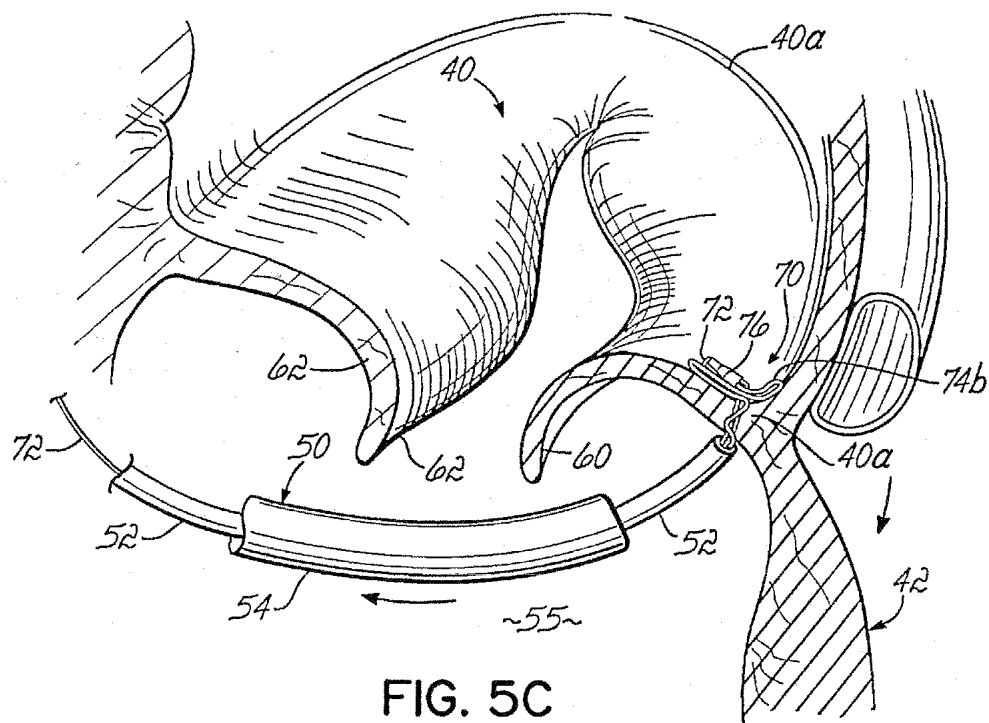


FIG. 5C

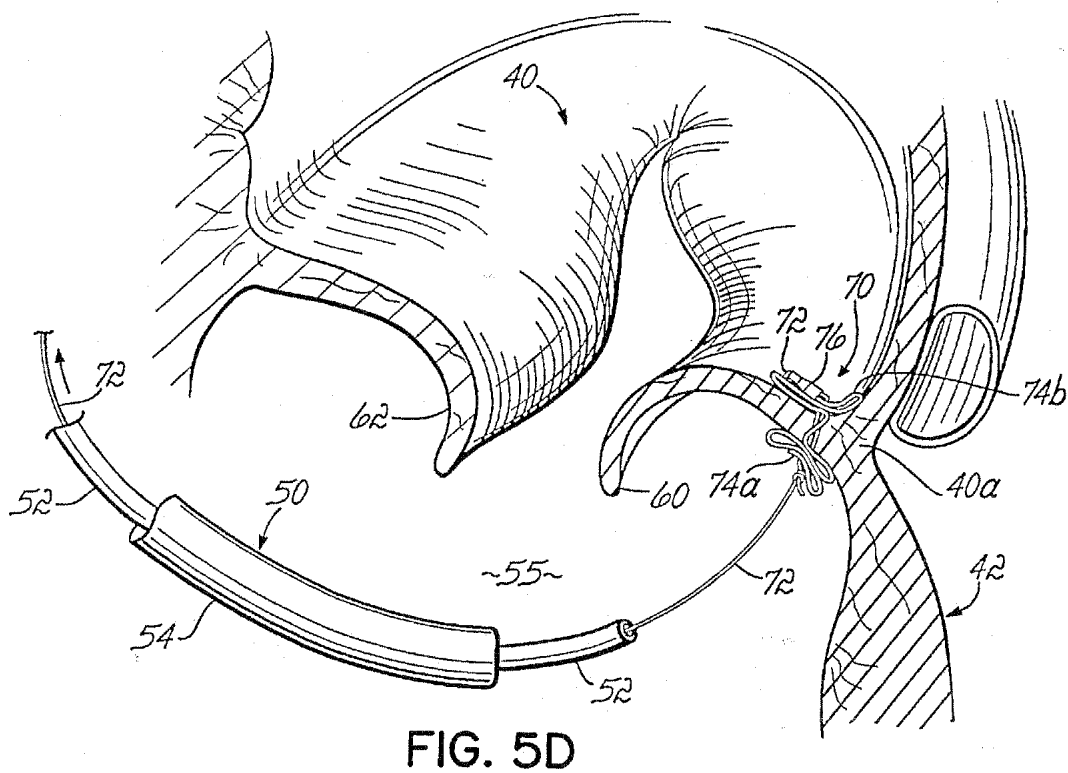
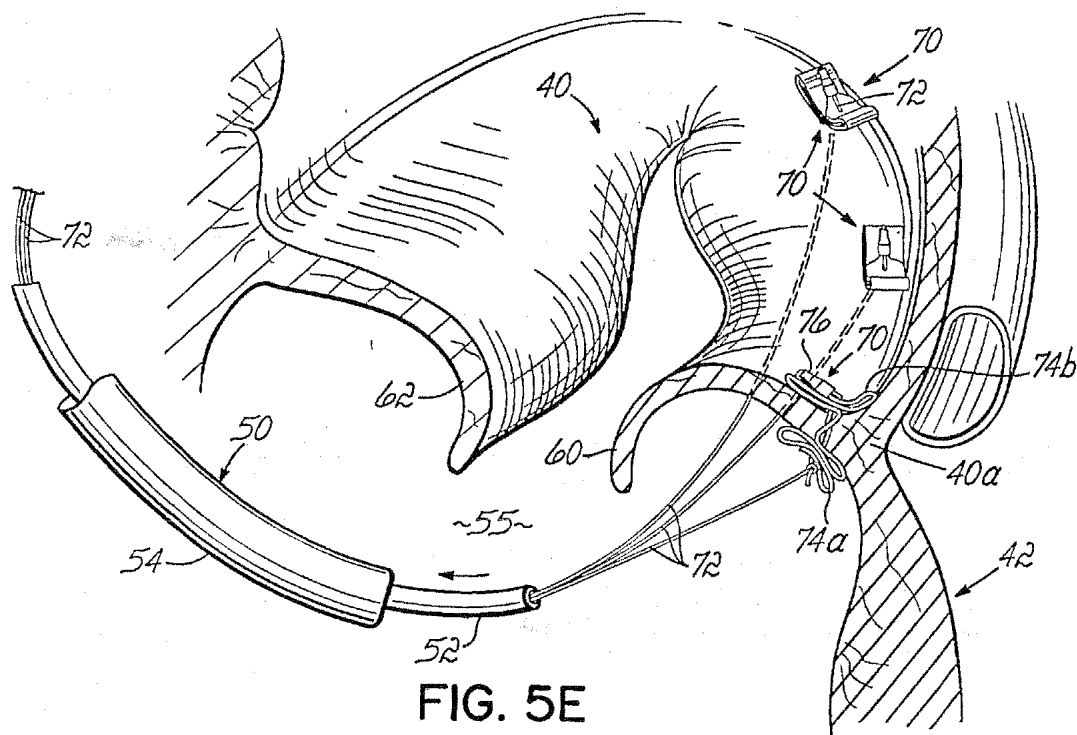
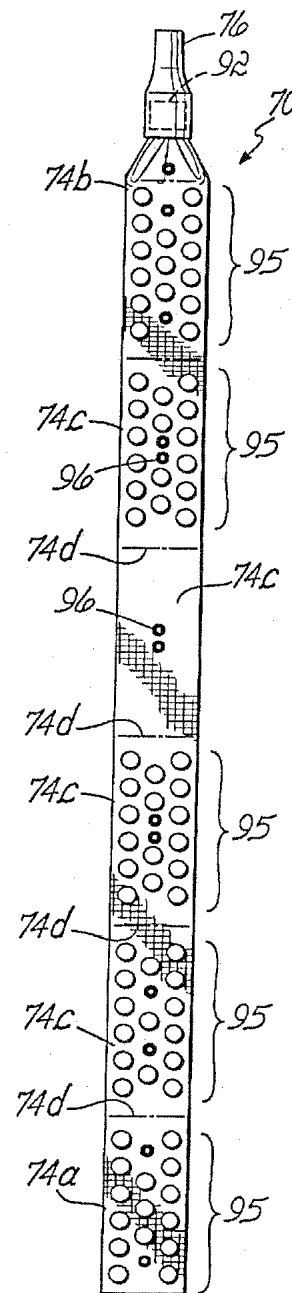
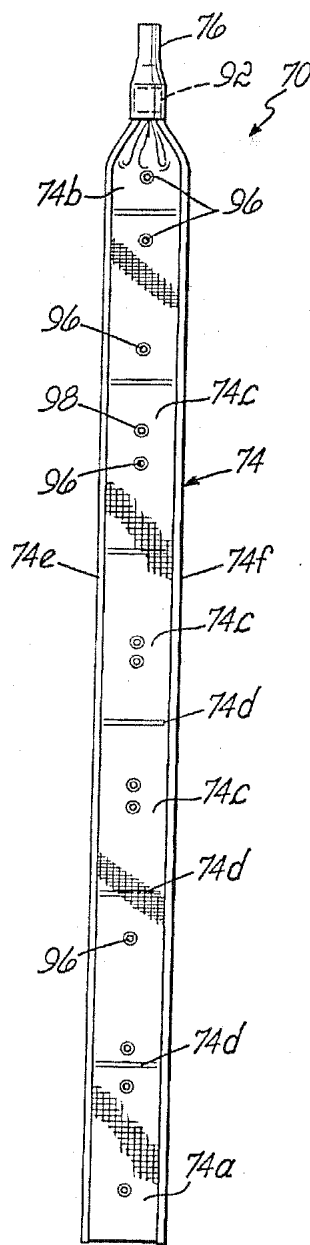
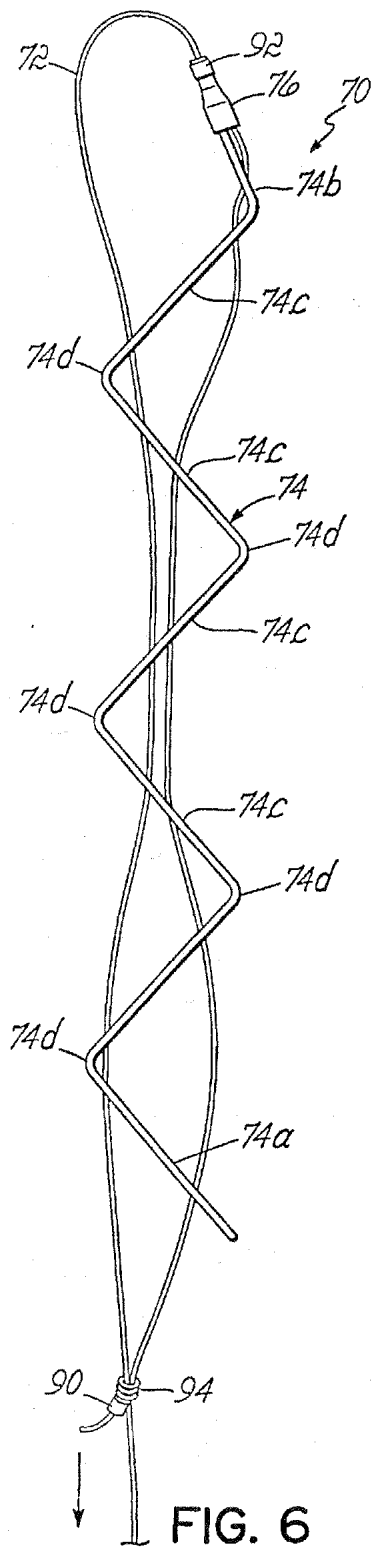


FIG. 5D

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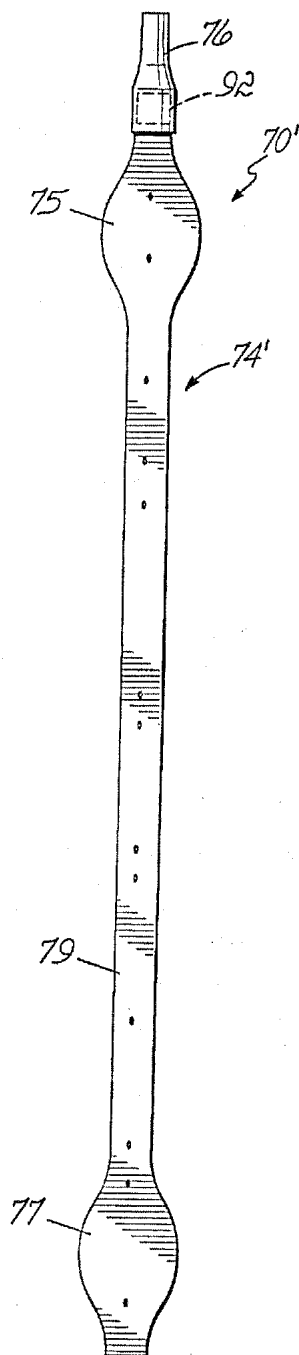


FIG. 7B

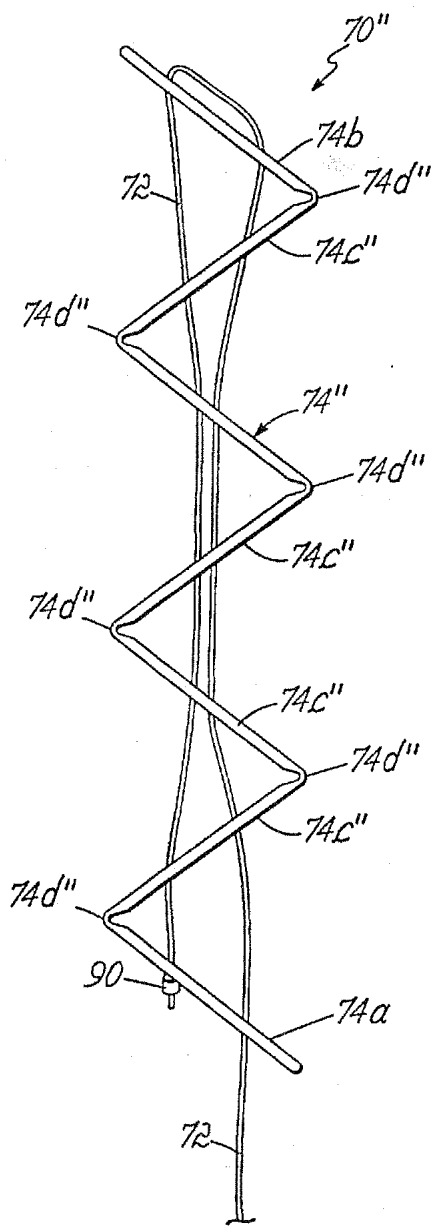


FIG. 7C

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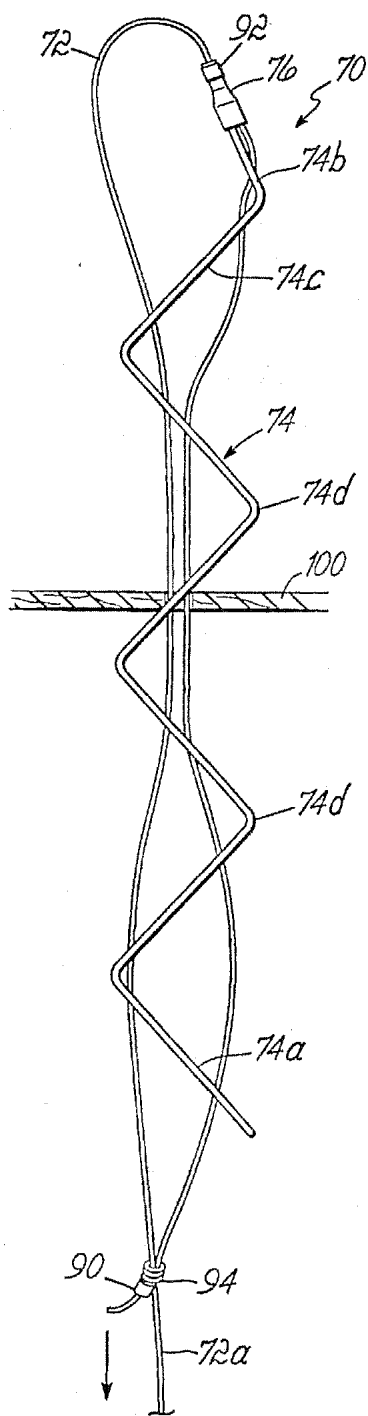


FIG. 8A

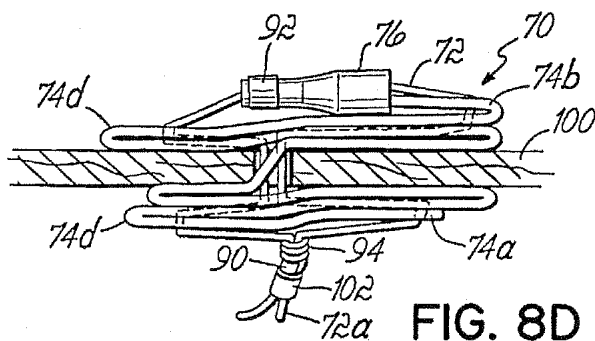


FIG. 8D

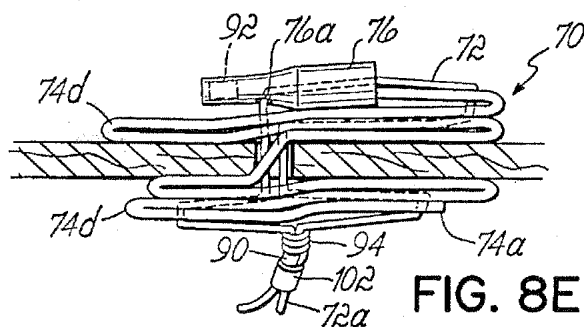


FIG. 8E

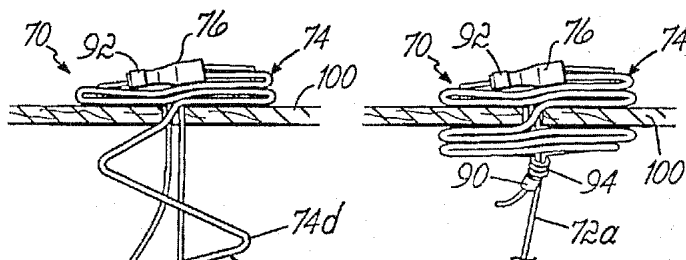


FIG. 8C

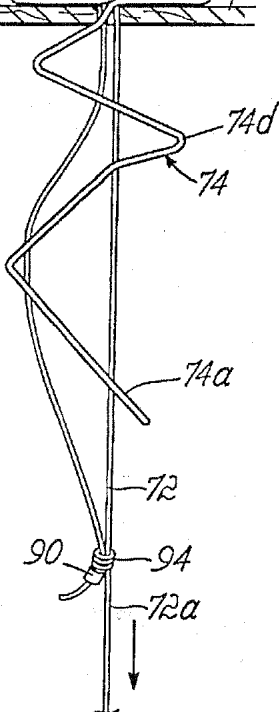


FIG. 8B

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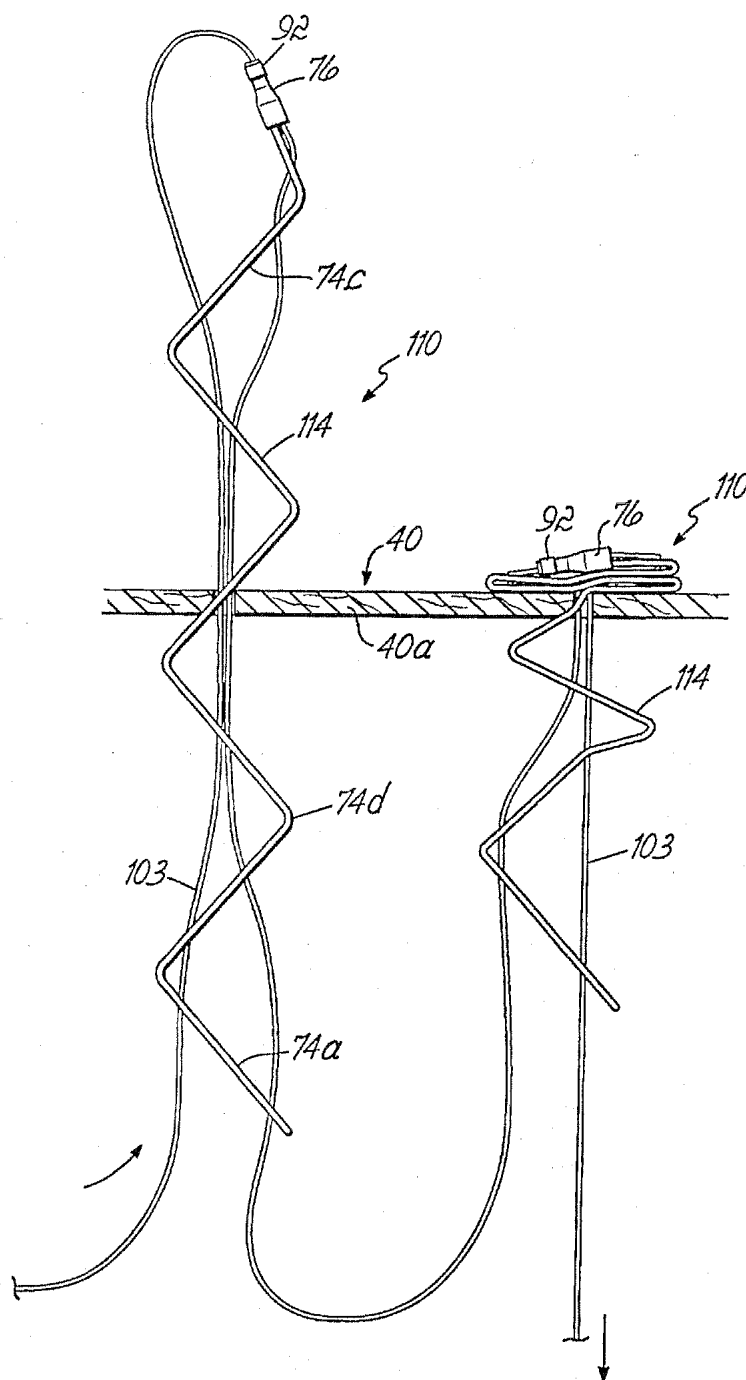


FIG. 9A

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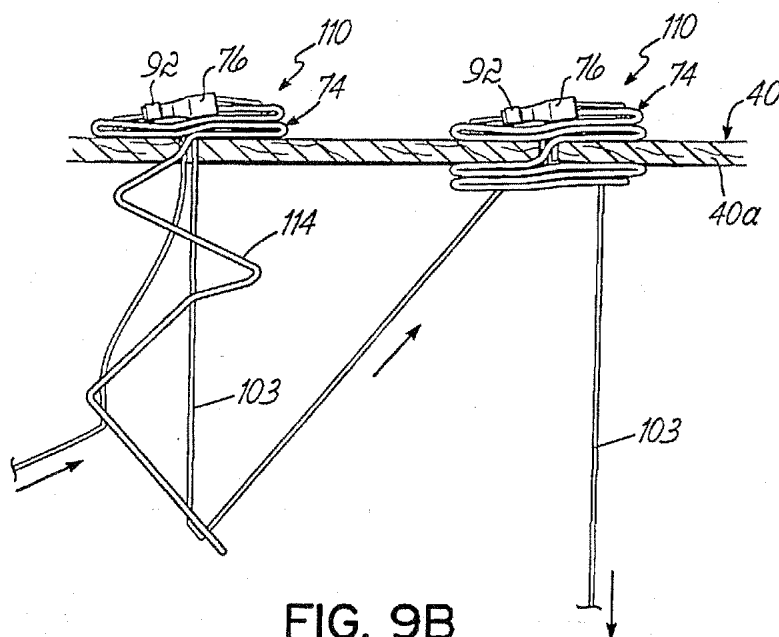


FIG. 9B

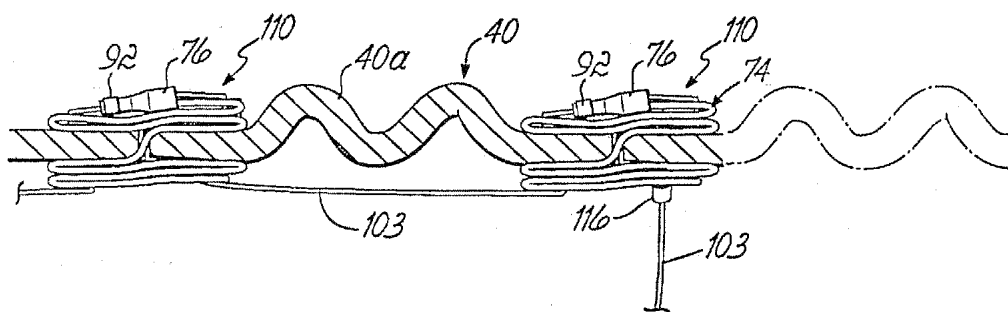
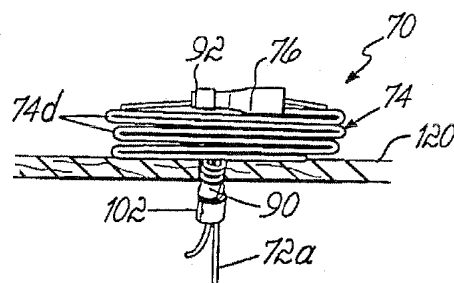
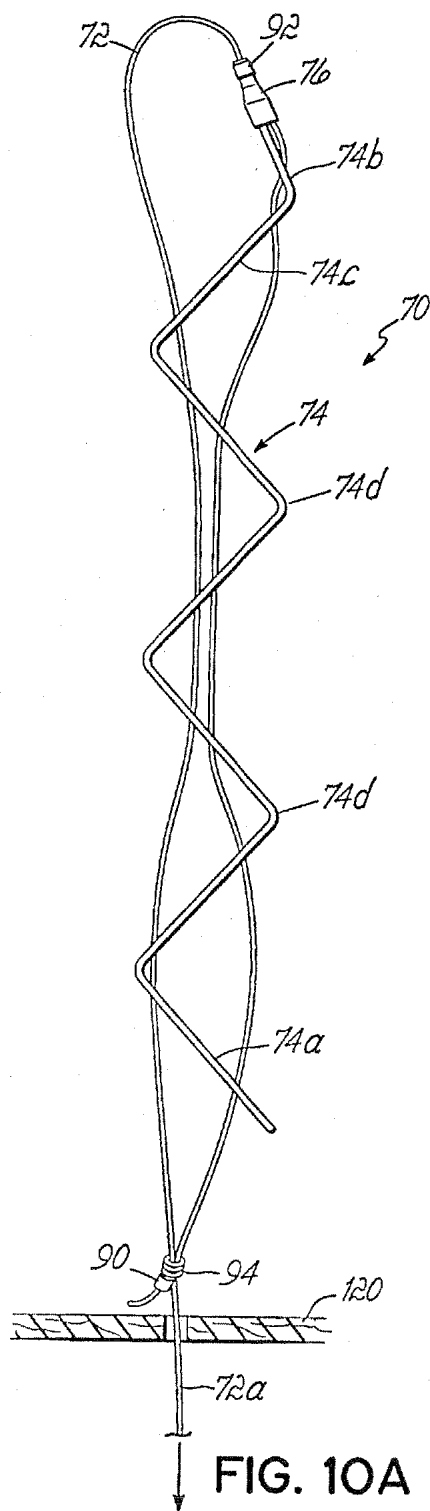


FIG. 9C

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/024897

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/011463 A2 (USGI MEDICAL INC [US]) 10 February 2005 (2005-02-10) paragraph [0053] - paragraph [0064]; figures 4-6	1-5,8,9, 16-20,22
X	WO 2005/013832 A (SCIMED LIFE SYSTEMS INC [US]; CHOPRA GOPAL [US]) 17 February 2005 (2005-02-17) abstract; figures 3,4	1,2, 16-20,22
A	WO 03/007796 A2 (NDO SURGICAL INC [US]; LAUFER MICHAEL D [US]; CERIER JEFFREY C [US]; C) 30 January 2003 (2003-01-30) abstract; figures 5-7	1-37

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

29 November 2006

Date of mailing of the international search report

06/12/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer:

Hansen, Soren

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/024897

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 38-55
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/024897

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 2005011463	A2	10-02-2005	AU	2003304379 A1	15-02-2005
			EP	1648279 A2	26-04-2006
WO 2005013832	A	17-02-2005	US	2005049634 A1	03-03-2005
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